

**Remarks**

Reconsideration of this Application is respectfully requested.

Claims 1-3 and 5-10 are pending in the application, with claims 1, 5 and 8 being independent claims. Claim 4 was cancelled in the amendment filed February 8, 2004.

The Applicant thanks Primary Examiner Glenn Dawson for the courtesy extended during a telephone interview with the Applicant's representatives Mary Tung and Jane Shershenovich during an interview regarding the present application on November 30, 2004. The Applicant also thanks Examiner Mendoza for the courtesy extended to Mary Tung during the telephone conversation on December 3, 2004. It was the understanding of the Applicant's representative that the Examiner would send a Supplemental Office Action prior to December 8, 2004. As an attempt to contact the Examiner on December 8, 2004 was not successful, nor did the Patent Application Information Retrieval (PAIR) system indicated the mailing of a supplemental Office Action as of December 8, 2004, the Applicant submits the present Reply based upon the Office Action mailed September 8, 2004, and does not reflect the substance of the phone discussion of December 3, 2004. The Applicant acknowledges that Examiner Mendoza referred the Applicant's representative to U.S. Patent No. 2,843,121 during the telephone conversation of December 3, 2004.

The Applicant thanks the Examiner for withdrawing finality of the Office Action mailed April 19, 2004. The Applicant also thanks the Examiner for withdrawing the rejection of claims 1-3 and 5-10 under 35 U.S.C. 103(a) as being unpatentable over Rudolph (U.S. Patent No. 5,265,595) in view of Dyrud *et al.* (U.S. Patent No. 5,819,731).

Based on the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

*Rejection of Claims under 35 U.S.C. 103(a)*

The Examiner has rejected claims 1-3 and 5-13 as being unpatentable over Norfleet (US Patent No. 6,418,929) "in view of Dyrud et al." (U.S. Patent No. 5,819,731). The Examiner states that "Norfleet teaches a mask having a means for being secured over the nose and the mouth of a patient, the improvement comprising: a pair of elastic bands, both ends of the each pair affixed at points of attachment to each of both sides of the mask, adjustably securable to the patient by pulling the ends anteriorly through the points of attachment (see fig.)." The Examiner stated that Norfleet fails to teach wherein the bands are extendible to loop over and around each ear of the patient.

The Examiner maintains that Dyrud et al. teaches a mask with common strap for looping around the ear of the patient for securing a mask. Examiner argues that it would have been obvious to one of ordinary skill in the art to modify the mask of Norfleet to include the strap of Dyrud et al. to prevent entanglement of the wearer's hair. The Examiner states that "Norfleet/Dyrud teaches wherein the elastic bands are affixed at four separate points on the mask (fig. 3); wherein the elastic bands are affixed at two separate points on the mask (figs. 1 & 2)."

Applicant respectfully disagrees. First, the Applicant confirms that the Examiner has found persuasive, Applicant's arguments set forth in the response filed July 19, 2004, that that the term "oxygen mask" is given patentable weight in the claims and provides structural elements to the claims (page 2, paragraph 2 of the Action mailed September 8, 2004).

The Applicant asserts that the claims and specification of Norfleet are drawn to an infant oxygen mask. The oxygen mask of Norfleet "includes a face mask and a strap assembly connected to the face mask and extendible around the head of the infant for holding the face mask snugly against the infant's face." (See the abstract, for example) The strap assembly is

oriented so that the straps are "positioned substantially above a corresponding ear of the infant" (see the abstract and col. 2, lines 11, 12, 30 and 31. In col. 4, lines 56-58). Norfleet discloses that "[i]o reduce contact with the infant's ears 82, each of the first and second junctures 75 and 80 is formed to have an elongated shape...." [Numerals referring to Figures 3 and 4 of the '929 Patent; emphasis added by Applicant; see col. 4, lines 56-62] Clearly, Norfleet teaches away from the Applicant's invention, as the Applicant's claims are drawn to a mask having *extendible bands which loop over and around each ear* of the patient in order to secure the mask to the patient. As the mask of Norfleet is designed to be used for infants (see col. 1 lines 16-42) the mask was designed to meet a long-existing need "for an oxygen mask for use on an infant that employs a strap which will secure the oxygen mask over the nose and mouth of the infant and which can be donned *over the infant's head* quickly and easily," (see col. 1, lines 43-47) and that Norfleet's main purpose is providing that "the oxygen mask remain securely in place over on [sic] the infant's face at all times *to prevent injury to the infant.*" (See *Norfleet*, col. 1, lines 40-47) Therefore, the Norfleet patent teaches away from the present invention [emphasis added by Applicant].

Regarding the Examiner's assertions that the combination of Norfleet and Dyrud teaches the claimed invention, the Applicant contends that the Examiner has not met his burden to establish a *prima facie* case of obviousness and that the combination of Norfleet and Dyrud do not teach each and every element of the present claimed invention. Applicant also confirms the Examiner's finding that the arguments presented in the previous paper were persuasive. Therefore, the Applicant maintains the arguments regarding Dyrud set forth in the Reply filed July 19, 2004, and incorporates said arguments by reference.

Applicant asserts that neither patent suggests the other, and thus one of ordinary skill in the art would not have motivation to combine the two references to arrive at the claimed invention without impermissible hindsight. While entanglement of the wearer's hair may be cited in Dyrud, Dyrud does not teach that this is a critical function provided by the invention, and entanglement of the user's hair was not mentioned in Norfleet. A reasonable artisan would not consider hair entanglement as a problem for use in an infant's mask. Norfleet teaches an oxygen mask to provide a tight fit for use in infants in general and neonatal infants in particular. Dyrud teaches a filtration mask but does not teach an oxygen mask. Additionally, Dyrud teaches a single band which extends around the back of the neck of the wearer (see Figure 1, (24) and col. 2, lines 59-62), clearly not a limitation of the claims of the present invention which require a pair of bands that loop around the ears (see Figure 1 of the present application). There is no teaching or suggestion provided by these two patents to combine the two features of their respective masks to arrive at the instant invention of the applicant. Therefore, without the guidance of the Applicant's specification, the Examiner could not have arrived at the Applicant's invention using Norfleet and Dyrud. Applicant maintains that the obviousness rejection made by the Examiner is merely impermissible hindsight reconstruction based upon the Applicant's disclosure.

MPEP § 2143, entitled "Basic Requirements of a *Prima Facie* Case of Obviousness" states,

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Applicant asserts that the Examiner has failed to meet his burden of establishing a *prima facie* case of obviousness because the first and third criteria have not been established.

a) *there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.*

The Examiner alleges that "it would have been obvious to one of ordinary skill in the art to modify the mask of Norfleet to include the strap of Dyrud *et al.* to prevent entanglement of the wearer's hair."<sup>1</sup> Applicant respectfully disagrees and asserts that upon reading the teaching of Norfleet, one of ordinary skill in the art would not be motivated to change the strap assembly to avoid entangling an infant's hair. Norfleet's main purpose is providing that the mask remain securely in place on the infant's face at all times to prevent injury to the infant. *See Norfleet*, Col 1, lines 43-47.

The Examiner also alleges that Norfleet teaches "an oxygen mask having a means for being secured over the nose and mouth of a patient, the improvement comprising: a pair of elastic bands, both end of each pair affixed at point of attachment to each of both sides of the mask; and fully capable of being adjustably securable to the patient by pulling the ends anteriorally through the point of attachment."

Applicant respectfully directs the Examiner to specification of Norfleet which explains the invention, including the detailed description of Figure 3.

"The present invention is directed to an oxygen mask for use on an infant. The oxygen mask includes a face mask and a 'strap assembly' connected to the face mask and *extendable around the head of the infant* for holding the mask against the infant's face." (col. 1, lines 51-

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<sup>1</sup> Applicant respectfully reminds the Examiner that the claimed invention does not include a strap as described in Dyrud. See the paper filed July 19, 2004 where the Applicants argued and the Examiner found persuasive, that Dyrud does not contain two straps to loop around the ears.

55). "The strap assembly includes an upper rear strap, a lower rear strap, and a plurality of forward straps." Col. 1, lines 65-66.

"The oxygen mask includes a face mask and a strap connected to the face mask and *extendable around the head of the infant* for holding the face mask snugly against the infant's face." (col. 2, lines 63-65; figure numbers deleted) "The oxygen mask is illustrated in Fig. 3 donned on the face of the infant. The oxygen mask includes a face mask and a strap assembly connected to the face mask and *extendable around the head of the infant.*" While Applicants have found many instances, as cited above, for a strap that is extendible "around the head of the infant" we were unable discern a description in Norfleet, of the claimed pair of bands "extendible to loop over and around each ear of the patient."

Finally, Norfleet teaches that "it will be appreciated by those of ordinary skill in the art that the strap assembly of the present invention can be constructed in a variety of different ways so long as the strap assembly functions as described herein." (col. 5, lines 10-13). Based on the teaching of Norfleet, as cited in the previous paragraphs, the strap assembly functions with a strap "extendable *around the head* of the infant." Therefore, Norfleet teaches away from changing to a strap assembly using two straps around the ears, as required in the present claims.

Applicant further contends that Norfleet teaches away from the claimed invention when it states that "to reduce contact with the infant's ears, each of the first and second junctures 75 and 80 is formed to have an elongated shape such that . . . when the mask and strap assembly are operably donned on the infant . . . [the straps cooperate] . . . with one another to prevent migration of the strap assembly along the infant's head." (col. 4, lines 56- 65). Thus, not only does the teaching avoid the infant's ears, but also the teaching ensures that the straps cooperate as to not migrate on the infant's head, thereby keeping the straps from the infant's ear.

Applicants assert that one of ordinary skill in the art, based on the teaching of Norfleet, as cited above, would not have been motivated at the time of the invention to modify the oxygen mask in Norfleet to arrive at the claimed invention because the purpose of Norfleet is to secure with a strap “around the head of an infant” at the same time, reducing contact with the infant’s ears.

**i) the proposed modification changes the principle of operation of Norfleet**

The Examiner alleged that one of ordinary skill in the art would modify the Norfleet mask to include bands extendible to loop over and around each ear of the patient.” Applicant assumes for the argument presented in this paragraph that the Examiner intended that one of ordinary skill in the art would have modified the mask in Norfleet to arrive at the claimed invention, which comprises a pair of bands, each band looping around the ear of a patient.

MPEP § 2143.01 states that if the “proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teaching of the references are not sufficient to render the claims *prima facie* obvious.” The suggested combination of references would require a substantial reconstruction and redesign of the elements in Norfleet as well as change the basic principle under which the Norfleet construction was designed to operation because there would no longer be a strap “extendible around the head of the infant.”

**b) the prior art reference (or references when combined) must teach or suggest all the claim limitations.**

Applicant also asserts that the prior art references do not teach or suggest all of the claim limitations. The Examiner alleges that Norfleet teaches “an oxygen mask having a means for being secured over the nose and mouth of a patient, the improvement comprising: a pair of

elastic bands, both end of each pair affixed at point of attachment to each of both sides of the mask; and fully capable of being adjustably securable to the patient by pulling the ends anteriorally through the point of attachment.” To support this allegation, the Examiner directs the Applicant to Figure 3 of Norfleet. After noting that Norfleet fails to teach bands extendible to loop over and around each ear of the patient, the Examiner cites Dyrud to cure this deficiency. It was already made of record that Dyrud teaches a mask with a common strap for looping around the ear of the patient, not a “pair<sup>2</sup> of elastic bands” as claimed in the instant invention. See the paper filed July 19, 2004, page 7.

It is also noted by the Applicant that if the strap of Norfleet were pulled anteriorally, as suggested by the Examiner, it would pull the mask away from the infant, thus circumventing the stated purpose of the Norfleet invention to secure the mask to the face of the infant.

Applicant asserts that the Examiner improperly rejected the claims of the instant invention because the cited prior art does not teach all of the claim limitations.

Based upon the preceding arguments, applicant therefore requests that the rejection of the claims under 35 U.S.C. 103(a) be withdrawn.

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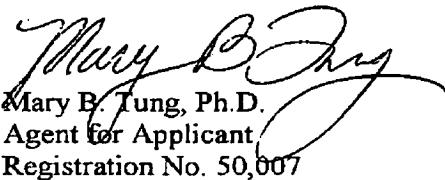
<sup>2</sup> Pair indicates two, not one band. “Elastic bands”, plural, also indicate more than one band.

*Conclusion*

Claims 1-3 and 5-13 are under consideration by the Examiner. In view of the above remarks, Applicant respectfully submits that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the objections and rejections. Applicant believes that a full and complete reply has been made to the outstanding Office action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,



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